

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Batra et al.).		·
Serial No.: 09/894,921)	Examiner:	
Docket No.: 20243CA)	Sharareh, S	Susunam Constant State S
Filed: June 28, 2001)	Art Unit: 1617	ATE SPONDER SP
For: "COMPRESSED TABLET FORMULATION")	,	CERTIFICA O · O · O · O · O · O · O · O · O · O ·
Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450			EXPRESS MAIL DSIT 1 - 1 L NO CV3. SISTIFY THAT TH ORESS MAIL "PR ORESS MAIL "P ORESS MAIL "P ANDRIA, VIRGI
INFORMATION DISCLOSURI	E STATI	EMENT	DATE OF DEPY EXPRESS MAI HEREBY C BEING DEPY SERVICE AS EX ON THE ABO ON THE ABO ALE MAILED BY DATE

Sir:

In compliance with 37 C.F.R. 1.97, submitted herewith on the attached form is a list of patents, publications, or other information. Copies of the cited references are enclosed. The submission and listing of these references is not to be construed as an admission that any of the submitted references is "prior art" with respect to the claimed invention. In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

Each item of information contained herein was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months before the filing of this information disclosure statement. The following are comments on three of documents in the attached list:

- 1. Document D3 is in Spanish, but translations of selected parts of the text are in parentheses. The document discloses certain HIV-1 protease inhibitors (especially saquinavir, ritonavir, indinavir and nelfinavir), and provides a brief discussion of clinical studies, resistance, adverse effects and metabolism. There is no mention of efavirenz. This document has essentially no relevance to the claimed subject matter.
- 2. Document D4 is also in Spanish, but translations of selected parts of the text are in parentheses. The document lists the principal groups of HIV antivirals

including efavirenz. This document has essentially no relevance to the claimed subject matter.

3. Document D5 is a portion of a 1995 edition of Remington's Pharmaceutical Sciences. Pages 859-863 closely correspond to Remington's Pharmaceutical Sciences, 19th edition, 1995, pp. 1616-1620, which is already of record. Pages 865-869 of Document C provide a general description of granulation methods. This document provides general technical information of interest as background with respect to the claimed invention, but is not otherwise relevant.

It is requested that the Examiner consider the cited references as part of the examination of the subject application, make the references of record, and return an initialed copy of the attached form with the next communication to Applicants.

Since this statement is being filed before the mailing of a first Office action after the filing of a Request for Continued Examination under 37 C.F.R. 1.114, no fee is believed to be due.

Respectfully submitted,

By:

Kenneth R. Walton, Reg. No. 32,951

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Date: November 10, 2003

	Substitute for form 1449A/PTO			COMPLE : IF KNOWN
Ø 3.	□ INFORMATION DISCLOSURE		Application Number	09/894,921
	STATEMENT BY	A DDI ICANIT	Filing Date	June 28, 2003
i '	STATEMENT DI	APPLICANI	First Named Inventor	Batra et al.
		,	Group Art Unit	1617
(use as many sheets as necessary)		Examiner Name	Sharareh, Shahnam J.	
Sheet	I	of 2	Attorney Docket Number	20243CA

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	,	Date of Publication of Cited Document MM-DD-YYYY
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	FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Office	Foreign Patent Document Number		Kind Code	Name of P of C	atentee or Applicar	nt Date of Publication Cited Documen MM-DD-YYY	t .
	DI	PCT	WO 96/22955	(if	A1	Merck & Co., It	nc.	08/01/2003	
	D2	PCT	WO 94/03440		A1_	Merck & Co., It	nc.	02/17/1994	
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^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Approved for use through 7/31/2006. OMB 0651-0031
SUBSTITUTE for PTO/SB/084 '08-03), Information Disclosure Statement by Applicant
Patent and P

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICAN COMPLE. 2 IF KNOWN Application Number 09/894,921 Filing Date June 28, 2003	
COLATERATERIO DA ANDI ICANSA	
(use as many sheets as necessary) First Named Inventor Batra et al. Group Art Unit 1617 Examiner Name Sharareh, Shahnam J.	
Examiner Name Sharareh, Shahnam J. Sheet 2 of RACE2 Attorney Docket Number 20243CA	
Sheet 2 of Attorney Docket Number 20243CA	

· 		NON PATENT LITERATURE DOCUMENTS
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
	D3.	"Los Inhibidores de La Proteasa Del VIH-1", 1997, http://www.prevenir.com/salud/sida/inhibid-proteasa.html.
	D4.	"Tratamiento con Antirretrovirales", 1997, http://www.prevenir.com/salud/sida/tratamiento.html.
	D5.	Remington's Pharmaceutical Sciences, 1995, pp. 859-869.
	D6.	L.M. Prescott, "Antimicrobial Agents and Chemotherapy", 1997, Vol. X, No. 12, http://thebody.com/bp/dec97/anti.html.
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Examiner Signature	Date Considered	·
Signature	Considered	1

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

SEND TO: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450. Computer generated form TDS Form* (IDS Folder), Merck & Co., Inc., 09/05/2003

P&T OFFICE ACK	NOWLED	GEMENT
ATTORNEY Kenneth R. Waltor		DATE 11/10/2003
CASE NUMBER/ 20243CA	SERIAL NUMBE 09/894,	921
June 28, 2001		
APPLICANT Batra et al.		, , , , ,
EV 323152342 US		
The Patent & Trademark stamped hereon, the dat checked below: AMENDMENT APPEAL AND FEE ASSIGNMENT BRIEF CERTIFICATE OF CO FINAL FEE LETTER REQUEST FOR F.F. INFORMATION DIS PTO 1449 & REFEF PETITION FOR EXT	CICENSE CLOSURE S'RENCES FENSION OF DRRECT	TATEMENT TIME & FEE

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